

## **Remarks**

### **I. Status and Nature of the Amendments**

Claims 1-24 are pending.

No amendments have been presented.

### **II. Claims Rejections -- 35 U.S.C. § 102**

Claims 1 to 23 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,375,028 to Smith.

Applicant respectfully traverses this rejection.

Claims 1 to 20 are directed to a separation device. In the illustrated embodiment, the separation device comprises a separation column 2 having an outlet 8, and a cover 4 which is removable for permitting introduction of a fluid containing a biomolecule, such as blood with nucleic acids, into separation column 2. A separation material 10, such as a silica membrane, is arranged in separation column 2 for isolating the biomolecule (e.g., nucleic acids) from the fluid (e.g., blood). A collection vessel 3 is provided for collecting the liquid exiting through outlet 8.

The interiors of collection vessel 3 and separation column 2 communicate with one another to permit pressure equalization between their interiors during separation processes, such as centrifugation. As a consequence, the separation device may be used without building up in collection vessel 3 excess pressure which could destroy separation material 10.

The Section 102(b) rejection is premised on the Examiner's characterization of Figure 22 of Smith as illustrating a separation device 50 containing a separation material 150. Applicant respectfully submits that Smith does not expressly or inherently support this characterization of Figure 22. Smith identifies reference number 150 as representing tissue specimens, not separation material. (Column 18, line 29) Tissue specimens 150

neither constitute nor function as separation materials. Rather, specimens 150 are placed in “container” 50 “for storage or processing.” (Column 18, lines 23-25) As described at column 18, lines 25-28 of Smith, container 50 is filled with a chemical fluid such as formaldehyde for disinfecting and preserving specimens 150 or other chemicals used for tissue decalcifier, staining, solvents, etc. (Column 18, line 66 to column 19, line 3) Fluid 41 is allowed to flow in and out of cavity 146 through openings 154. In no manner does Smith describe tissue specimens 10 as capable of separating biomolecules from a liquid, or as otherwise constituting or serving as a separation material.

The Examiner argues at pages 5-6 of the final Office Action that the absence of a disclosure of a separation step with regard to Figure 22 of Smith is not relevant, because separation “is a method limitation and not a structural limitation.” In response, Applicant respectfully submits that the substance of remarks presented above and on November 18, 2005 is not directed to a process limitation, but to an express structural limitation of the claimed separation device. The separation device of claims 1 to 20 features a separation material. The descriptor “separation” characterizes a feature/property that the material possesses, i.e., the capability to perform a separation function, especially for separating biomolecules from a fluid. Accordingly, in the context of the device as claimed, the term “separation” denotes a structural property of the material. This structural property is not shared by tissue specimens 150 of Smith.

The Examiner also argues that Figures 20 and 20A disclose “different variations of the same embodiment” as Figure 22 of Smith, and relies on Figures 20 and 20A for their illustrations of a filter 140. (Final Office Action, page 3, lines 12-14) Applicant respectfully submits that the embodiments of Figures 20/20A and 22 are not “variations” of each other, but are separate and distinct embodiments that serve different purposes, possess different structures, and operate in different manners from one another.

As described above, the embodiment depicted in Figure 22 is a storage vessel used for the storage of a specimen. Fluid 41 surrounds conical wall section 142 to submerge tissue samples 150 in cavity 146. No filter is present in Figure 22, and modification of the storage container 50 to include filter 140 of Figures 20/20A would

serve no purpose. Container 50 of Figure 22 does not act as a separator. Additionally, if the embodiment of Figure 22 were modified to include filter 140, the elevated level of fluid 41 surrounding conical wall section 142 would permit fluid 41 to freely pass through openings 154 of conical wall section 142 without being filtered, thereby negating the purpose of filter 140 and destroying any motivation to add filter 140 to Figure 22.

Conversely, the embodiment illustrated in Figures 20 and 20A lacks a pressure-equalization connection between a separation column and a collection vessel. Smith is devoid of motivational teaching for modifying the embodiment of Figures 20/20A to include such a connection. The alleged pressure-equalization connection of Figure 22, i.e., openings 154, serves the purpose of permitting fluid 41 to flow through conical wall section 142. As described above, the embodiment of Figure 22 is designed as a storage container in which fluid 41 surrounds conical wall section 142 and may pass through openings 154. In contrast, in Figures 20/20A, fluid 41 is situated below conical wall section 142 to permit filter 140 to function as intended. Because the fluid level depicted in Figures 20/20A is below conical wall section 142 (out of necessity in order to permit gravitational forces to drain fluid through filter 140), creating fluid-passage openings in conical wall section 142 of Figures 20/20A would not serve any purpose disclosed by Smith.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 102 rejection of claims 1 to 20.

Claims 21 to 23 recite a separation method that features centrifuging a fluid in the separation device to separate fluid from a material while permitting pressure equalization. As established above, Smith does not disclose the separation device of the invention and, therefore, cannot anticipate the method as claimed in claims 21-23.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 102 rejection of claims 21 to 23.

### **III. Claims Rejections -- 35 U.S.C. § 103(a)**

Claim 24 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith in view of U.S. Patent No. RE 35,071 to Lewis.

Applicant respectfully traverses this rejection.

The deficiencies of Smith vis-à-vis claim 21 are described above. Because claim 24 depends from claim 21 and includes all of the distinguishing features thereof, Smith likewise is deficient with regard to claim 24. Lewis, which has been cited for disclosing a step of centrifuging bodily fluids, does not overcome the deficiencies of Smith.

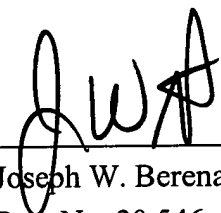
For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection of claim 24.

### **IV. Concluding Remarks**

Having now responded to all of the Examiner's rejections, Applicant respectfully submits that the present application is in condition for Allowance, and earnestly solicit early notice of favorable action. The Examiner is respectfully invited to contact the undersigned with respect to any issues regarding this application.

Respectfully Submitted,

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